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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,071	09/12/2001	Mike Farwick	212532US0X	1541

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/950,071

Applicant(s)

FARWICK ET AL.

Examiner

Christian L Fronda

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,10-12,16,17,19-22,26 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-6,10-12,19-22,26 and 43-47 is/are allowed.
- 6) ☒ Claim(s) 16,17,38-40,48 and 49 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1, 3-6, 10-12, 16, 17, 19-22, 26, and 38-49 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is directed to all possible polynucleotides comprising at least 23 consecutive nucleotides of SEQ ID NO:1 with any biological function. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide having a sequence of SEQ ID NO: 1. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than the polynucleotide sequence having at least 23 consecutive nucleotides of SEQ ID NO:1 for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claim to recite that the polynucleotide encodes a RodA cell division protein may overcome this rejection.

4. Claims 48 and 49 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated polynucleotide comprising at least 23 consecutive nucleotides of SEQ ID NO: 1 which functions as a primer in PCR or any isolated polynucleotide comprising at least 23 consecutive nucleotides of SEQ ID NO: 1 which functions as an oligonucleotide probe.

The state of the prior art as exemplified by Sambrook et al. ('Types and uses of oligonucleotide probes'. In: Molecular Cloning A laboratory manual, 1989 second edition, pp. 11.3-11.10.) is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Therefore, predictability of which 23mer oligonucleotide probe will hybridize specifically and preferentially to a polynucleotide with the nucleotide sequence of SEQ ID NO: 1 is extremely low. Furthermore, determining specific primers to specifically amplify a polynucleotide with a nucleotide sequence of SEQ ID NO: 1 is determined empirically and the effects of specifically amplifying SEQ ID NO: 1 and no other polynucleotides with biological functions yet to be determined is unpredictable.

The specification does not provide guidance with respect to the specific nucleotide sequence of any probe or primer comprising at least 23 contiguous nucleotides or SEQ ID NO: 1 that will specifically and preferentially hybridize to or amplify a nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 1. The amount of experimentation to determine the specific nucleotide sequence of any probe or primer comprising at least 23 contiguous nucleotides or SEQ ID NO: 1 that will specifically and preferentially hybridize to or amplify a nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 1 is enormous. Such experiment entails performing extensive hybridization or PCR experiments with every 23mer probe or primer possible to determine which 23mer probe or primer will specifically and preferentially hybridize to or amplify a nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 1.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the oligonucleotide probe or primer which will specifically and preferentially hybridize to or amplify a nucleic acid molecule that has the nucleotide sequence of SEQ ID NO: 1. Without such a guidance, the experimentation left to those skilled in the art is undue.

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Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 17 is vague and indefinite because it is unclear whether the recited "washing in 5X SSC at a temperature from 50° to 68° C" is considered a stringent hybridization condition.
Amending the claim to recite washing in 0.5X SSC at a temperature of 68° C may overcome this rejection.
7. Claims 38-40 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolating or collecting the produced L-amino acid.

Conclusion

8. Claims 1, 3-6, 10, 11, 12, 19-22, 26, 43-47 are allowed.
9. Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. A signed copy of the 1449 for the IDS dated 2/11/2002 was attached to the Advisory Action dated 6/18/2003. The signed copy is again attached to the instant Office Action for convenience.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196. CLF

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